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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/665,395 | 09/22/2003 | John Butler | 08203.0005-04000 | 4412 |
| 22852 7590 02/17/2009 FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER | | EXAMINER | | |
| LLP | | | RAMANA, ANURADHA | |
| 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413 | | | ART UNIT | PAPER NUMBER |
| | | | 3775 | |
| | | | | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 02/17/2009 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | Application No. | Applicant(s) | | | | |
|--|---|---------------|--|--|--|--|
| | 10/665,395 | BUTLER ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Anu Ramana | 3775 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
| Status | | | | | | |
| 1) Responsive to communication(s) filed on 19 De | ecember 2008. | | | | | |
| • | action is non-final. | | | | | |
| <i>,</i> — | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | |
| | closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | |
| Disposition of Claims | | | | | | |
| 4)⊠ Claim(s) <u>1,6-9,14-25,27-36,55-58 and 61</u> is/are pending in the application. | | | | | | |
| 4a) Of the above claim(s) <u>9,17-25 and 27-36</u> is/are withdrawn from consideration. | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6)⊠ Claim(s) <u>1,6-8,14-16,55-58 and 61</u> is/are rejected. | | | | | | |
| 7) Claim(s) is/are objected to. | | | | | | |
| 8) Claim(s) are subject to restriction and/or | election requirement. | | | | | |
| Application Papers | | | | | | |
| 9)☐ The specification is objected to by the Examiner. | | | | | | |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | | |
| a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. | | | | | | |
| | | on No | | | | |
| | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). | | | | | | |
| | | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| | | | | | | |
| Attachment(s) | | | | | | |
| 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date | | | | | | |
| 3) Notice of Draftsperson's Patent Brawing Review (PTO-946) 5) Notice of Informal Patent Application | | | | | | |
| Paper No(s)/Mail Date <u>10/29/2008</u> . 6) Other: | | | | | | |

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DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 58 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation "a taper in a plane normal to a plane formed by the distal ring in a deployment position" is deemed to be new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 58 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "a taper in a plane normal to a plane formed by the distal ring in a deployment position" renders the claim vague and indefinite because the structural relationship being claimed by the Applicant is unclear.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6-8, 14, and 55-57 are rejected under 35 U.S.C. 102(b) as being anticipated by Klein et al. (US 4,488,877).

Klein et al. disclose a retractor (10, 12) including: a sleeve or retracting member 12; a receiver 44 so that the retractor may be held by an insertion tool or forceps; a forceps 100; and a distal ring member 18 mounted to the retracting member (Fig. 1, col. 2, lines 60-68, col. 3, lines 1-38 and col. 4, lines 5-11). Also see Fig. 14, col. 8, lines 51-68 and col. 9, lines 1-9 of Martinez et al. (US 4,776,843) incorporated by reference in Klein et al.

Claims 1, 6-8, 14, 55-58, and 61 are rejected under 35 U.S.C. 102(b) as being anticipated by Mueller et al. (US 5,810,721).

Mueller et al. disclose a retractor including: a retracting member 96; a distal ring member 82 mounted to the retracting member, the distal ring member 82 being made of a flexible material; and an obturator or insertion tool 88 wherein the insertion tool 88 has a groove for completely receiving a distal portion of the retractor (Figs. 10A, 10B, and 10C, col. 6, lines 27-51, col. 10, lines 34-67 and col. 11, lines 1-2).

Regarding claims 58 and 61, Mueller et al. disclose the insertion tool to have inward facing or tapered surfaces 90 that define a groove and an opening, the opening facing the wound opening during deployment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

⁽a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having

ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein et al. (US 4,488,877).

Klein et al. disclose all elements of the claimed invention except for the specific ranges of dimensions.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed forceps 100 with the claimed ranges of dimensions, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mueller et al. (US 5,810,721).

Mueller et al. disclose all elements of the claimed invention except for the specific ranges of dimensions.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed the Mueller et al. insertion tool with the claimed ranges of dimensions, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Response to Arguments

Applicant's arguments submitted under "REMARKS" in the response filed on October 29, 2008 have been fully considered.

Applicant's arguments with respect to the rejections of claims 1, 6-8, 14, 55, and 57 under 35 USC 102(b) over Klein et al. are not persuasive. The Examiner notes that "a central longitudinal axis" is the longitudinal axis passing through a center of the bent portion of forceps 100. The Examiner also notes that the insertion tool of Klein has "a

unitary shaft portion" and a distal end portion including arms 101 and 102 wherein arms 101 and 102 define a retractor receiving portion (103, 104) and the retractor receiving portion defines an opening facing the wound opening during deployment.

The Examiner also notes that the manner or method in which an apparatus is to be utilized is not germane to the issue of patentability of the apparatus itself (In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967)).

Regarding the rejections under 35 USC 102(b) over Mueller et al., it is noted that Mueller et al. disclose an insertion tool which receives the distal ring 82 such that the distal ring intersects a central longitudinal axis of the insertion tool. Further, the distal ring 82 extends generally in the direction of the longitudinal axis (see Fig. 10B).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR February 9, 2009

/Anu Ramana/ Primary Examiner, Art Unit 3775